

**Notice of Allowability**

Application No.

10/024,894

Examiner

Matthew F. DeSanto

Applicant(s)

WOJCIK, STEVEN

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/11/05.
2. ☒ The allowed claim(s) is/are 1,3,12-14 and 17.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 11/30/05.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stanley Weinberg on November 30, 2005.

The application has been amended as follows:

Claim 1:

An inserter for a low-profile angled infusion set, the low-profile inserter comprising:

an inserter housing having a bottom wall, and a distal end defining an opening therein;

a retainer slideably mounted in the inserter housing for movement between retracted and extended positions in a direction substantially parallel with the bottom wall, the retainer being adapted to releasably receive the infusion set, including a cannula and an insertion needle, the cannula and insertion needle defining an insertion axis;

a tension spring extending between two points for biasing said retainer toward said extended position, said tension spring being movable between an expanded

position when said retainer is in said retracted position, and a contracted position when said retainer is in said extended position;

a first release button for releasing said tension spring from said expanded position, said first release button movable in a direction substantially normal to said insertion axis;

a second release button for releasing the infusion set from the retainer; and

a base member connected to the inserter housing, the base member having a lower surface that is adapted to contact a user's skin surface, the lower surface and the bottom wall forming an acute angle, wherein the cannula and the insertion needle are guided to be inserted subcutaneously along the insertion axis at said acute angle with respect to the skin surface.

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Claim 14:

An inserter for an infusion set, the inserter comprising:

an inserter housing defining an opening in a distal end thereof;

a retainer slideably connected to the inserter housing for movement between retracted and extended positions, the retainer being adapted to releasably receive the infusion set including a cannula and an insertion needle, the cannula and the insertion needle defining an insertion axis;

a biasing member connected between the retainer and the inserter housing for biasing the retainer toward the extended position, said biasing member being expanded when said retainer is in said retracted position, and contracted when said retainer is in said extended position;

a first release button for releasing said biasing member from said compressed position, movable in a direction substantially normal to said insertion axis;

a second release button for releasing the infusion set from the retainer; and

a base attached to a lower surface of said inserter housing defining an acute angle with respect to said inserter housing, for guiding the insertion needle and the cannula to be inserted subcutaneously in skin of a user, along the insertion axis and at an acute angle with respect to the skin.

Claim 17.

A method for inserting an insertion needle and a cannula into skin of a user, comprising the steps of:

providing an inserter housing having a bottom wall, a distal end defining an opening therein, and a base member attached to the bottom wall proximate the distal end, said base member including a lower surface adapted to contact the skin and defining an acute angle with said bottom wall;

slidably mounting a retainer within said inserter housing, movable between a retracted position and an extended position, said extended position being substantially parallel with said bottom wall of said inserter housing;

mounting the cannula and the insertion needle in said retainer to define an insertion axis;

providing a tension spring between two points for biasing said retainer toward said extended position, movable between an expanded position and a contracted position;

releasing said tension spring by pressing a release button proximate said distal end of said inserter housing, in a direction substantially normal to the insertion axis, thereby releasing said spring to move from said expanded position to said contracted position and move said retainer to said extended position, whereby said insertion needle and said cannula are guided to be inserted subcutaneously in the skin at said acute angle with respect to the skin; and

depressing a second release button to release the cannula and the insertion needle from the retainer.

### **Reasons for Allowance**

2. The following is an examiner's statement of reasons for allowance:

The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was an inserter for a low profile angled infusion set, wherein the low-profile inserter comprises a first and second release button, wherein the first release button releases the tension spring that controls the retainer and the second release button releases the infusion set from the retainer as well as the method of using the low-profile inserter with regards to the first and second release buttons.


The independent claims also include other patentable subject matter in combination with the other elements or steps of the claim not mention in the above paragraph.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

  
Matthew DeSanto  
Art Unit 3763  
December 8, 2005

  
MATTHEW F. DESANTO  
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